

WEEK ENDING OCTOBER 3, 2014

# **OPP Weekly Activity Report**

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## PESTICIDE RE-EVALUATION DIVISION

Registration Review; Pesticide Dockets Opened for Review and Comment. On September 24, 2014, the EPA opened the dockets for 18 cases, which include conventional, antimicrobial, and biopesticide chemicals, for a 60-day comment period. Preliminary work plans and supporting documents that outline anticipated risk assessment and data needs are available in each chemical docket identified in the Federal Register notice at <u>www.regulations.gov</u> in docket EPA-HQ-OPP-2014-0565. The chemicals with docket openings listed in this notice are: 2-(thiocyanomethylthio) benzothiazole (Sandra O'Neill, (703) 347-0141); 1,3-Propanediamine, N-(3-aminopropyl)-N-dodecyl-(PAD) (Tina Pham, (703) 308-0125); 3(2H)-Isothiazolone, 4,5-dichloro-2-octyl- (DCOIT) (SanYvette Williams (703) 305-7702); Bacillus thuringiensis (Jeannine Kausch, (703) 347-8920); Cyhalofopbutyl (Jolene Trujillo, (703) 347-0103); Diclofop-methyl (Marianne Mannix, (703) 347-0275); Etoxazole (Julia Stokes, (703) 347-8966); Fenpropimorph (Donna Kamarei, (703) 347-0443); Fluroxypyr, 1-methylheptylester (Benjamin Askin, (703) 347-0503); GABA & LGA (Menyon Adams, (703) 347-8496); Imazapic (Ricardo Jones, (703) 347-0493); Imazaquin (Wilhelmena Livingston, (703) 308-8025); Polyoxin D Zinc Salt (Manying Xue, (703) 305-6198); Noviflumuron (Dana Friedman, (703) 347-8827); Streptomyces lydicus WYEC (Kathleen Martin, (703) 308-2857); Tebufenpyrad (Susan Bartow, (703) 603-0065); Triallate (Katherine St. Clair, (703) 347-8778); and Zinc pyrithione (Sandra O'Neill, (703) 347-0141). This notice also announces two case closures and the Agency's intent not to open a registration review case for two additional chemicals. The registration review case for 3 H-1,2 Dithiol-3-one,4,5-dichloro- (RYH-86) (case 5033) is being closed for nonpayment of maintenance fees for the two remaining registrations. The "Notice of Registration Review Case Closure for RYH-86" is available in the docket EPA-HQ-OPP-2008-0767 at http://www.regulations.gov. The tepraloxydim (case 7257) registration review case is being closed because the last products were canceled in the Federal Register notice on August 6, 2014 (79 FR 45798) (FRL-9914-09). The "Notice of Registration Review Case Closure for Tepraloxydim" is available in the docket EPA-HQ-OPP-2014-0246 at http://www.regulations.gov. The Agency will not open registration review cases for vinclozolin (case 2740) and mepanipyrim (case 7042) because there are no registered products containing these active ingredients. The cancellation order for the last vinclozolin registration was issued in the Federal Register notice on August 13, 2014 (79 FR 47454) (FRL-9914-00). (LaTanya Moody, 703-308-8022).

Registration Review; Availability of Draft Human Health and Ecological Risk Assessments. On September 24, 2014, a notice was published in the Federal Register announcing the availability of draft human health and ecological risk assessments for the registration review of 2 conventional chemicals. As part of the registration review process, the Agency has completed draft human health and

ecological risk assessments, including an endangered species assessment, for all uses of these pesticide chemicals. These assessments are available in each chemical docket identified in the Federal Register notice at <a href="www.regulations.gov">www.regulations.gov</a> (EPA-HQ-OPP-2014-0594) with a 60 day public comment period. The chemicals with draft human health and ecological risk assessments appearing in this notice are: 2-EEEBC (Debacarb) (Roy Johnson, (703) 347-0492); and Isoxaben (Christina Scheltema, (703) 308-2201) (LaTanya Moody, 703-308-8022).

Registration Review Notice of Availability for Proposed Interim Decisions. On September 24, 2014, a notice was published in the Federal Register announcing the availability of 10 proposed interim registration review decisions for conventional chemicals. These decision documents are available in each chemical docket identified in the Federal Register Notice at <a href="www.regulations.gov">www.regulations.gov</a> (EPA-HQ-OPP-2014-0628) with a 60-day public comment period. The chemicals with proposed interim decisions appearing in this notice are: 4-CPA (Miguel Zavala, (703) 347-0504); Allethrins (Marianne Mannix, (703) 347-0275); Fluazinam (Avivah Jakob, (703) 305-3328); Flumetsulam (Katherine St. Clair, (703) 347-8778); Flutolanil (Garland Waleko, (703) 308-8049); Hexaflumuron (Ricardo Jones, (703) 347-0493); Iron Salts (Katherine St. Clair, (703) 347-8778); Piperalin (Matthew Manupella, (703) 347-0411); Quinclorac (Margaret Hathaway, (703) 305-5076); and Triflumizole (Steven Snyderman, (703) 347-0249). (LaTanya Moody, 308-8022).

Registration Review Final and Interim Decisions. On September 24, 2014, a notice was published in the Federal Register announcing the availability of 7 registration review decisions. These decision documents are available in each chemical docket identified in the Federal Register Notice at <a href="www.regulations.gov">www.regulations.gov</a> (EPA-HQ-OPP-2014-0651). The chemicals with interim decisions appearing in this notice are: Ancymidol (Christina Scheltema, (703) 308-2201); DEET (Susan Bartow, (703) 603-0065); Denatonium saccharide (Cathryn Britton, (703) 308-0136); and Metofluthrin (Veronica Dutch, (703) 308-8585). The chemicals with final registration review decisions are: Dioctyl sodium sulfosuccinate (Garland Waleko, (703) 308-8049); Polybutene resins (Joel Wolf, (703) 347-0228); and Undecylenic acid (Garland Waleko, (703) 308-8049). (LaTanya Moody, 703-308-8022).

MCPA Final Work Plan Signed. On September 25, 2014, the Final Work Plan for MCPA was signed. MCPA is a post-emergence herbicide that is registered for use for selective control of broadleaf weeds in various agricultural and non-agricultural settings. Agricultural use sites include barley, flax, grasses grown for seed, oats, pastureland, peas, rye, and wheat. Non-agricultural use sites include uncultivated fields, ornamental and residential lawns, and turf. The Agency plans to require several environmental fate, ecological effects, and human health studies for MCPA through a Registration Review Data Call-In currently slated to be issued in winter 2014 (Khue Nguyen, 703-347-0248).

MCPB Final Work Plan Signed. On September 25, 2014, the Final Work Plan for MCPB was signed. MCPB is a postemergence phenoxy herbicide registered for use to control annual and perennial broadleaf weeds in peas, spearmint, and peppermint. MCPB is not registered for any non-agricultural uses. The Agency plans to require several environmental fate, ecological effects, and human health studies for MCPB through a Registration Review Data Call-In currently slated to be issued in winter 2014 (Khue Nguyen, 703-347-0248).

Thiophanate Methyl & Carbendazim Final Work Plan Signed. On September, 26, 2014, the Final Work Plan (FWP) for thiophanate methyl & carbendazim (TM/MBC) was signed. MBC is a pesticide active ingredient and also a metabolite, environmental degradate, and the pesticidally active moiety of TM. TM is a systemic benzimidazole fungicide registered for use to manage a variety of diseases on various crops as well as on turfgrass and ornamental plants. MBC is a systemic benzimidazole fungicide registered for use as a materials preservative in paints, caulks, and other building supplies. It also has a conventional pesticide use as an ornamental tree injection. The public comment period on the Preliminary Work Plan closed on May 27, 2014, and the comments submitted resulted in a change to the planned data needs. The FWP will be posted to the public docket (EPA-HQ-OPP-2014-0004) (Carissa Cyran, 703-347-8781).

Ethephon Draft Risk Assessment (DRA) Kick-off Meeting. On September 30, 2014, PRD met with the ethephon registration review team members from EFED, HED BEAD, and RD to discuss the current status of ethephon, the proposed timeline for completing the DRA, and the next steps. All of the data requirements that were called-in under registration review has been received and sent to the science divisions for review. Ethephon, an organophosphonate, is a plant growth regulator. It is registered for use on a number of terrestrial food, feed, and nonfood crops, greenhouse nonfood crops, and outdoor plants. Ethephon is also registered for use in residential settings. The team will meet again in six months to discuss the current use patterns, and determine whether a focus meeting is needed with the registrants to address any remaining uncertainties. (Wilhelmena Livingston, 703-308-8025)

Chlorothalonil Registration Review Meeting Held. On September 30, 2014, the OPP registration review team met with representatives from Syngenta to discuss the inhalation risk assessment, inhalation study guidelines in rat and avian species, and field volatility and terrestrial field dissipation protocols. OPP agreed to consider a waiver that Syngenta will be submitting to address the data call-in requirement for the avian acute inhalation study. Chlorothalonil is a broad spectrum, non-systemic protectant pesticide mainly used as a fungicide to control fungal foliar diseases of vegetable, field, and ornamental crops. (Matthew Manupella, 703-347-0411)

Fenamiphos End-Use Date Extended – In an October 1, 2014 Federal Register Notice (FRL-9917-19), the agency granted the Golf Course Superintendents Association of America's (GCSAA) request to extend the end-use date for fenamiphos products from October 6, 2014 to October 6, 2017. GCSAA reported that golf courses had purchased the majority of the fenamiphos stocks produced during the last year of the phase out in 2008, due to the lack of a viable alternative to control nematodes in turf. EPA was not aware of the volume of stocks in the hands of golf courses when it established the October 6, 2014 end-use date. The agency believes the most cost-effective and efficient option to exhaust the remaining stocks is to use the stocks as directed on product labeling rather than transporting hazardous substances over potentially lengthy distances to a pesticide disposal facility. While fenamiphos is not subject to registration review, a company has responded to the fenamiphos FFDCA DCI order with data to support import tolerances for several commodities. (Tracy Perry, 703-308-0128)

Bifenazate Draft Risk Assessment Kick-off Meeting. On October 1, 2014, PRD met with the bifenazate registration review team members from EFED, HED, BEAD and RD to discuss the current status of the chemical, the expedited timeline for completing the DRA, and next steps. The data called in for registration review has been received. In addition, updated assessments were recently completed for a PRIA action for new uses of bifenazate. Bifenazate is a selective carbazate miticide/insecticide that is registered for use to control the motile stage of mites in agricultural and non-agricultural sites including on bearing and non-bearing fruit and vegetable crops, cotton, conifer plantations, ornamentals, and in greenhouses, indoor/outdoor residential, commercial, institutional, and recreational areas. The team will meet again for a check-in and will also decide if a focus meeting with the registrant, Chemtura/MacDermid Agricultural Solutions, is necessary. (Garland Waleko, 308-8049)

PRD Meets with Avitrol Corporation on Labeling Issues: Representatives from Avitrol Corporation met with PRD to discuss the labels of products containing 4-aminopyridine. 4-Aminopyridine is registered to control nuisance bird species in areas such as airports, where birdstrikes can disable airplane engines. Issues were raised to the company in response to incidents and concerns from public interest groups about labeling, with a focus on increasing protection of non-target species, particularly requirements for the handler to stay on site after setting out treated grain. In follow-up to Agency concerns, Avitrol Corporation will provide a summary of the stewardship efforts it has undertaken to educate handlers on the correct use of 4-aminopyridine products with recently approved labeling that reflects RED mitigation measures. A follow-up meeting is planned to discuss possible label improvements and the process going forward. (Moana Appleyard, 703 308-8175)

### ANTIMICROBIALS DIVISION

Bovine Corneal Opacity and Permeability On September 19, 2014, a conference call was held between EPA scientists (Anna Lowit, Tim McMahon) and David Allen (NICEATM) to discuss revisions to the Bovine Corneal Opacity and Permeability assay (BCOP). The purpose of this teleconference was to discuss whether the BCOP assay (currently used to classify Category I and II eye irritants) could be expanded to include Category III irritants. The use of the BCOP assay for identification of Category III irritants was originally included in the Antimicrobial Division's eye pilot alternative testing strategy, but was not included in the final policy document, based on concern that Category III irritants were overpredicted by the assay. Dr. Allen will provide additional data and analysis supporting the use of the BCOP for identification of Category III eye irritants (Tim McMahon, 308-6342)

Antimicrobials Division participates in the US Global Biocides Regulation

Conference on September 25 and 26, 2014 in Washington D.C. Tim McMahon presented a talk entitled "US EPA Office of Pesticide Program's 21st Century Vision for Enhancing Integrated Approaches to Testing and Assessment and Strategy for Communication", which provided a broad overview of the efforts in the Office of Pesticide Programs to transform the risk assessment paradigm through use of alternative test methods (in vitro/in silico) and computational toxicology methods. Collaborations within the federal government through ICCVAM and NICEATM as well as international collaborations were presented. Examples of specific projects within OPP (alternate eye testing strategy for antimicrobial cleaning products and Threshold of Toxicological concern for antimicrobial pesticides) were also presented. Mark Hartman and Mark Perry provided an overview of efficacy requirements and the antimicrobial testing program (ATP). Melba Morrow talked about EPA and FDA collaborations during a session on EPA and FDA regulatory jurisdiction of food use antimicrobial products. Jennifer McLain presented an overview of the OECD Task Force on Biocides, including future challenges such as work sharing. Other topics discussed during the conference included the EU Biocidal Product Regulation, disinfectant registration in Canada, and the regulation of treated articles in various countries. The conference concluded with a panel discussion on the challenges of working in a global market. (Jennifer McLain 308-0293).

AD Provides Input to OW and ORD on CCA Consumer Awareness Program. On Thursday September 25, 2014, AD hosted a conference call with Office of Water (OST) and Office of Research and Development to share information and lessons learned on the development of the 1986 chromated copper arsenate (CCA) Consumer Awareness Program (CAP) and the 2011 joint Consumer Product Safety Commission publication for existing CCA-treated structures. OW and ORD are considering similar outreach efforts to educate citizens about cyanotoxins and

harmful algal blooms in drinking water and recreational waters. The CAP is a voluntary program established in 1986 (and later updated in 2001) by the manufacturers of CCA products to inform consumers about the proper handling, use and disposal of CCA-treated wood. The 2011 CPSC/EPA publication provides consumers with information on the disposal and handling of existing structures made from CCA-treated wood. (Lance Wormell, 703-603-0523)

PMRA Consults EPA for Regulatory Guidance on Anti-Mold Stickers. On Tuesday September 30, 2014, AD regulators participated in a conference call with Canada's Pesticide Management Regulatory Agency regarding the regulation of anti-mold stickers and antimicrobial packing sheets. As part of PMRA's ongoing effort to develop a policy on treated articles, PMRA requested the call to get EPA input on how EPA approaches the domestic use and importation of products intended to prevent mold growth on materials in transit (e.g., shoes being shipped to the US from overseas). EPA clarified that such products require registration if the production/sale/use/distribution occurs within the US whereas products produced/sold/used/distributed overseas do not trigger the EPA requirement for registration. EPA will continue to provide input to PMRA as it develops its treated article policy. (Lance Wormell, 703-603-0523; John Hebert, 703-308-6249; Joel Wolf, 703-347-0228; Tina Pham, 703-308-0125)

AD Discusses Registration Review DCI with Peroxy Compounds Task Force. On September 22, 2014, AD along with members from ToxSAC met with representatives from the Peroxy Compounds Task Force (PCTF) to discuss registration review exposure data call-in requirements. The discussion focused on the PCTF's request for agency consideration of an alternative toxicity endpoint for peroxy compounds (hydrogen peroxide and peracetic acid) exposure data, based on a recently submitted 90-Day Inhalation Toxicity Study in Rats (completed by the Cefic Peroxygen Sector Group). AD will complete a review of the 90-Day Inhalation Toxicity Study and present significant findings to ToxSAC. Once the agency reaches a consensus on the toxicity endpoint for peroxy compounds, the agency will relay the decision to the task force and determine an appropriate time extension date for outstanding exposure data dependent on the endpoint. (Tina Pham, 308-0125)

Antimicrobial Registration Review DCIs Issued. AD issued a Generic Data Call-In (GDCI) for seven registration review chemical cases during Q4 of FY2014: Ethylene oxide (ETO), Dowicil 100 (CTAC), Decyl isononyl dimethyl ammonium chloride (DIDAC), 1,3,5-Triazine-2,4-diamine, N-cyclopropyl-N'-(1,1-dimethylethyl)-6-(methylthio)- (Irgarol), M-Cresol, Xylenol, and ortho-phenyl phenol & salts (oPP and salts). The GDCIs require the submission of specific data needs identified in the registration review final work plans for these cases. (Donna Kamarei 703-347-0443, Tina Pham 703-308-0125, and SanYvette Williams 703-305-7702)

Zinc Pyrithione (ZnPT) Preliminary Work Plan Posted for Comment. In a Federal Register Notice dated September 24, 2014, EPA announced the availability of the preliminary work plan for the registration review of the ZnPT Case (Case 2480). This case includes one active ingredient: zinc pyrithione (PC Code 088002). ZnPT is registered for use as a pesticide in materials preservation, and antifouling coatings and is also regulated by the FDA in non-pesticidal products (e.g., shampoos). The material preservation uses include repeat use food contact polymers, carpet fibers and backing, building materials, textiles, non-marine paints as and coatings, and plastics. The preliminary work plan is available in docket EPA-HQ-OPP-2014-0158 at <a href="www.regulations.gov">www.regulations.gov</a>. The 60-day public comment period closes on November 24, 2014. (Sandra O'Neill, oneill.sandra@epa.gov)

3(2H)-isothiazolone, 4,5-dichloro-2-octyl (DCOIT) Preliminary Work Plan Posted for Comment. The preliminary work plan for the antimicrobial pesticide 3(2H)isothiazolone, 4,5-dichloro-2-octyl (DCOIT) was posted on September 24, 2014 as part of the registration review process. In the preliminary work plan, the agency outlined the studies needed to support the registration review risk assessments which will be required through a data call-in. DCOIT is registered for use for incorporation into products such as adhesives, coatings, fuels, metal working fluids (MUP only), resin emulsions, paints and various other specialty industrial products (as a preservative); and, as a microbiocide in pulp/paper mills, cooling water systems, oil field operations (MUP only), industrial process waters and air washers systems. The compound is also registered for use to treat wood products (seasoned/unseasoned forest products and various finished wood products). The preliminary work plan and other documents relevant to the registration review case are located in docket EPA-HQ-OPP-2014-0403 at www.regulations.gov. The 60-day public comment period closes November 24, 2014. (SanYvette Williams, williams.sanyvette@epa.gov)

Fenpropimorph Preliminary Work Plan Posted for Comment. In a Federal Register Notice dated September 24, 2014, EPA announced the availability of the preliminary work plan (PWP) for the registration review of fenpropimorph (case # 5112). Products containing the active ingredient fenpropimorph can be applied by non-pressure wood treatment through dip or spray to control sapstain, prevent mold and decay on green or freshly cut lumber and wood products such as logs, poles, posts, composites, veneers, wood chips and saw dust. The preliminary work plan is available in docket EPA-HQ-OPP-2014-0404 at <a href="www.regulations.gov">www.regulations.gov</a>. The 60-day public comment period closes November 24, 2014. (Donna Kamarei, 703-347-0443)

1,3-Propanediamine, N-(-3-aminopropyl)-N-dodecyl- (1,3-PAD) Preliminary Work Plan Posted for Comment. In a Federal Register Notice dated September 24, 2014, EPA announced the availability of the preliminary work plan (PWP) for the registration review of 1,3-PAD case no. 5109. The active ingredient, 1,3-

Propanediamine, N-(-3-aminopropyl)-N-dodecyl, PC code 067300, is currently registered for use on non-porous, inanimate surfaces as a sanitizer and disinfectant in public access, commercial, institutional and industrial premises, applied by mopping, foaming generator, and mechanical sprayer. It is also registered for use as a preservative in metal working fluids (enclosed) and oil field flood water systems, via metering pump application. The preliminary work plan is available in docket EPA-HQ-OPP-2014-0406 at <a href="www.regulations.gov">www.regulations.gov</a>. The 60-day public comment period closes November 24, 2014. (Tina Pham, 308-0125)

2-(Thiocyanomethylthio)-benzothiazole (TCMTB) Preliminary Work Plan Posted for Comment. In a Federal Register Notice dated September 24, 2014, EPA announced the availability of the preliminary work plan for the registration review of the TCMTB Case (Case 2625). This case includes one active ingredient: 2-(thiocyanomethylthio) benzothiazole (PC Code 035603). The agency is assessing TCMTB as a dual-use chemical that has both antimicrobial and agricultural uses. As an antimicrobial pesticide, TCMTB is used largely as a materials preservative (e.g., leather products and hides, pulp/paper products, surface coatings, adhesives, caulks, and sealants), and also as a wood preservative and in industrial processes and water systems. As an agricultural pesticide, TCMTB is used for seed treatment (on rice, safflower, and cotton). The preliminary work plan is available in docket EPA-HQ-OPP-2014-0405 at <a href="www.regulations.gov">www.regulations.gov</a>. The 60-day public comment period closes on November 24, 2014. (Sandra O'Neill, oneill.sandra@epa.gov)

Organic Esters of Phosphoric Acid (OEPA) Final Work Plan Signed and Posted to Docket. The final work plan for the antimicrobial pesticide Organic Esters of Phosphoric Acid (OEPA) was completed on September 30, 2014 as part of the registration review process. In the final work plan, the agency outlined the studies needed to support the registration review risk assessments which will be required through a data call-in anticipated to be issued in September 2015. OEPA is registered for use as a materials preservative in a wide variety of materials such as carpets, paints, air filters and textiles. The final work plan and other documents relevant to the registration review case are located in docket EPA-HQ-OPP-2013-0373 at <a href="www.regulations.gov">www.regulations.gov</a>. (SanYvette Williams, <a href="williams.sanyvette@epa.gov">williams.sanyvette@epa.gov</a>)

Lithium Hypochlorite Final Work Plan Posted to Docket. On August 29, 2014, the Final Work Plan (FWP) for the registration review of lithium hypochlorite was signed. Lithium hypochlorite is registered for use as a sanitizer/algaecide in swimming pools and as a sanitizer for spas/hot tubs. No public comments were received during the 60-day public comment period on the lithium hypochlorite Preliminary Work Plan, thus no modifications were made to the anticipated data needs or registration review timeline. The agency does not anticipate needing any new data to support the registration review of lithium hypochlorite; furthermore, the agency anticipates only performing a new ecological risk

assessment on swimming pool uses of lithium hypochlorite. The lithium hypochlorite FWP can be found in docket EPA-HQ-OPP-2013-0606 at <a href="https://www.regulations.gov">www.regulations.gov</a>. (Donna Kamarei, 703-347-0443)

Potassium Hypochlorite Final Work Plan Posted to Docket. On August 29, 2014, the Final Work Plan (FWP) for the registration review of potassium hypochlorite was signed. Potassium hypochlorite is registered for use as a sanitizer/disinfectant with a wide range of uses sites such as agricultural premises and equipment, irrigation systems, food handling/storage establishment premises and equipment, commercial, institutional and industrial premises and equipment, human drinking water systems, industrial processes/ water systems, swimming pools, and spas. No public comments were received during the 60-day public comment period on the potassium hypochlorite Preliminary Work Plan, thus no modifications were made to the anticipated data needs or registration review timeline. The agency does not anticipate needing any new data to support the registration review of potassium hypochlorite; furthermore, the agency believes that potassium hypochlorite is similar to and can be considered with the chemicals in case 0029, sodium and calcium hypochlorite. No risk assessments are considered necessary for any of the three compounds since EPA has concluded that the currently registered uses of the hypochlorites will not result in unreasonable adverse effects to human health or the environment. The potassium hypochlorite FWP can be found in docket EPA-HQ-OPP-2014-0157 at www.regulations.gov. (Donna Kamarei, 703-347-0443)

4,5-Dichloror-1,2-dithiol-3-one (RYH-86) Registration Review Case Closure Issued. In a Federal Register Notice dated September 24, 2014, EPA announced the Registration Review Case Closure of 4,5-Dichloror-1,2-dithiol-3-one (RYH-86). RYH-86 is an antimicrobial pesticide which was previously registered for use as an industrial slimicide for closed system injection into pulp and paper slurry in paper mills. On July 24, 2009, EPA published the Cancellation of Pesticides for Non-Payment of Year 2009 Registration Maintenance Fees in the Federal Register (74 FR 36699) (FRL-8427-4), which included among other products, the only two active U.S. registrations for RYH-86. Due to the cancellation order issued affecting the two remaining RYH-86 product registrations in the United States, the agency has found that it is not necessary to complete new risk assessments for the case, and is therefore closing the registration review case for RYH-86. A copy of the 2009 cancelation order and the notice of registration review case closure can be found in docket EPA-HQ-OPP-2008-0767 at <a href="https://www.regulations.gov">www.regulations.gov</a>. (Donna Kamarei, 703-347-0443)

### FIFI D & FXTFRNAL AFFAIRS DIVISION

OPP Staff Attends the Avance Center's First Annual Latino Health Disparities
Conference. On September 25, FEAD fellow and OPP's Special Emphasis Program
Team member Ana Rivera-Lupiáñez attended the Avance Center's First Annual
Latino Health Disparities Conference. The conference, sponsored by the Milken
Institute School of Public Health at George Washington University, brought
together researchers, practitioners and advocates committed to addressing
health disparities that impact Latino immigrant communities. The meeting also
offered training and capacity-building for the conduct of innovative research
and implementation of interventions that are responsive to the changing needs of
the Latino population. (Ana Rivera-Lupiáñez, 308-6841)

## BIOLOGICAL & ECONOMIC ANALYSIS DIVISION

BEAD Attends First US/Global Biocides (Antimicrobials) Regulation Conference in Washington, DC. A two-day US/Global Biocides Regulatory Conference recently held in Washington DC, on September 25-26, 2014. BEAD microbiologist Jafrul Hasan attended the Day 2 of the conference. The conference debuted the first time in DC, brought together experts from North America (NA), Asia and the European Union (EU) to discuss the latest developments in the regulation of biocides (antimicrobials). More specifically, the day 2 focused on global perspectives encompassing the data requirements for hard surface and food contact products, the biocide product regulation and an in-depth overview of regulation of treated articles in NA, Asia and the EU. In addition, Dr. Jennifer Mclain of AD also provided an overview of the role of OECD Task Force on biocide activities. At the end of every session, an interactive QA session followed. It was emphasized to continue various efforts of harmonization so that the methods, data and the regulation are comparable and/or on the same page. (Jafrul Hasan, 410-305-2657)

Briefing on Strategic Sourcing of Laboratory Supplies. John Bashista, Director of Office of Acquisition Management (OAM), provided a management level briefing on the National Blanket Purchase Agreement (BPAs) for laboratory supplies and the development of national contract vehicles to provide equipment maintenance for laboratory equipment across the country. The national BPAs, expected to be awarded shortly, will leverage EPA's buying power for laboratory supplies through a centrally-managed, decentralized executed solution. The solution will enable agency level tracking and reporting, ease of use, and competitive pricing. The goal is to have 100% BPA utilization, a steady increase in utilization over the life of the contracts (years 2-5), and a continuous level of improvement to ensure effective utilization of the BPAs. OAM plans to hold separate briefings for purchase card holders, key analysts, and contract

officials at the laboratories. (Susan Lawrence, 410-305-2954 and Thuy Nguyen, 410-305-2905)

BEAD Provides Briefing to AD About Plans and Programs for Upcoming ASTM Meeting in New Orleans. The ASTM International (American Society for Testing and Materials) is the largest standards development organization where methods are reviewed and approved through a rigorous consensus-based process. Two Agency initiated methods, ASTM E2839-11 (Production of Clostridium difficile spores) and ASTM standard E2896-12 (Quantitative Petriplate Method or QPM for Towelettes), are currently being considered by ASTM for revisions. BEAD plans to move forward with the proposed revisions for ASTM Standard E2896-12 at the Fall Meeting of ASTM, scheduled to be held in New Orleans on October 8-10, 2014. BEAD Microbiology Laboratory team leader Jafrul Hasan, the technical contact for the ASTM Methods, briefed this week the management and team leader of the Product Science Branch, Antimicrobials Division, shared the program agendas and explained a few ASTM methods undergoing revisions or being proposed which may be of interest to EPA. In addition, BEAD also explained the details of proposed revisions to ASTM E2996-12 (QPM method) and the data generated at MLB employing the proposed revisions. The briefing was effective as AD appears to be in agreement with BEAD as to the strategy and emphasis on certain proposed methods in an effort to showcase a productive meeting at ASTM. (Jafrul Hasan, 410-305-2657)

## INFORMATION TECHNOLOGY & RESOURCES MANAGEMENT DIVISION

OPP FOIA Request Status Report for Sept 22- 26, 2014								
Requests Received		Requests Closed			Requests Open			
FY14	This Week	FY14	FYTD	This Week	FY14	Prior Years	Total	
526	8	336	463	20	190	160	350	
							_	

(Ana Espinoza, 703-347-0102)

PRIA Fees Resource Directory Published. The ITRMD Web Team worked with FEAD to publish the PRIA Fees web area in the Drupal Web CMS. Redirects have been implemented from the pesticides website to redirect the public to the PRIA Fees resource directory home page. Please visit the PRIA Fees resource directory home page at <a href="http://www2.epa.gov/pria-fees">http://www2.epa.gov/pria-fees</a> for more information. (Les Hoot, 703-305-0876)

4th Quarter Registration Review Pesticide Dockets Added to Chemical Search. The ITRMD Web Team worked with PRD to post the Q4 Registration Review Pesticide Dockets opened for review and comment in Chemical Search and the comment period will close on November 24, 2014. Preliminary work plan for these chemicals were also added to Chemical Search. For information on these or other chemicals, please visit the OPP's Chemical Search Database. (Miriam Organic, 703-605-0583; Christine Tran, 703-305-1577)

## BIOPESTICIDES & POLITION PREVENTION DIVISION

**BPPD Webinar Focuses on Creating Tick Safe Schools**. On September 30, BPPD's Center of Expertise (CoE) for School IPM hosted the second in a series of school IPM webinars. Thomas Mather (University of Rhode Island), Kathy Murray (Maine Department of Agriculture), Christine Dunathan (Friends Community School, MD), and Marcia Anderson, (CoE) presented information on ticks of concern, their biology, integrating tick management into a school IPM plan, and a decisionmaking rationale for tick management. They also presented information on habitat modification to reduce the risk of tick-borne diseases, common tick control measures, and a wealth of tick resources. The 160+ attendees included representatives from 74 school districts and childcare centers, 35 departments of health, and two tribes. This webinar was part of a regular series being conducted by the CoE to help schools implement and improve their IPM programs. The next webinar, The Basics of School IPM, will be October 21, 2014, at 2 PM Eastern (www.epa.gov/pestwise/events/sipm-webinars.html). Following each webinar, the CoE disseminates attendee contact information, organized by state, to our Regional School IPM Coordinators to help them focus their follow-up outreach. (Marcia Anderson, 214-665-6679)

BPPD Participates in BPIA Registration Workshop On September 30 – October 1, over a dozen BPPD and ITRMD staff participated in training for BPIA members and interested non-members to support their efforts to submit complete PRIA packages. The workshop addressed key regulatory challenges and encouraged best practice for the registration of biopesticides. The event also provided a platform for participants to work together on submission processes, and included aspects such as electronic submissions and data waivers. Participants were very interested in the session on electronic submissions, and found the hands-on demonstration of the e-dossier builder by Amy Roberts to be particularly helpful. (Kimberly Nesci, 308-8269; Sheryl Reilly, 308-8269)

## **ENVIRONMENTAL FATE & EFFECTS DIVISION**

<u>Meeting on Honey Bee Colony Survey Design Elements</u>. From Wednesday, September 24 through Friday, September 26, 2014, EFED staff participated in stakeholder discussions in Florida to identify study design elements for a proposed

survey of honey bee colonies as they move through their pollination/honey production cycle. The Florida Fruit and Vegetable Association (FFVA) through its Florida Specialty Crop Foundation (FSCF) and in cooperation with Dr. Jamie Ellis at the University of Florida is in the process of developing a framework for examining stressors on honey bee colonies in Florida agricultural production areas, focusing on citrus, blueberries and cucurbits (watermelons). The intent is to develop a study framework that can be expanded to a national level. Participating in the discussions were growers/applicators, beekeepers, and state and federal regulatory agencies. EFED provided the group with an overview of its risk assessment process for bees as well as study design elements, which EPA typically examines in colony-level field studies. The FFVA/FSCF hope to fund a pilot study that will serve as a proof of concept for a broader study proposal that will be submitted to USDA for possible funding. (Tom Steeger, 703-305-5444).

<u>Training Session on Models</u>. On October 2, EFED held the first of four "hands-on" weekly training sessions on computer models used by EFED. This first session covered the development and use of chemical and management inputs for models, a discussion of EFED's ground water models SCIGROW and PRZM-GW and surface water models, FQPA Index Reservoir Screening Tool (FIRST) and the Pesticides in Flooded Agriculture Model (PFAM). (Ron Parker, 703-305-5505).

## HEALTH EFFECTS DIVISION

Science Advisory Board Teleconference on Ethylene Oxide: On September 30, the Chemical Assessment Advisory Committee of EPA's Science Advisory Board (SAB/CAAC) held a teleconference on ethylene oxide (ETO). The meeting was in part a planning session for the main meeting in November, but also included short presentations by public speakers on concerns they had with the ETO review. The public presenters, who were largely registrant representatives, focused primarily on modeling issues and sought to modify the charge questions to the SAB to insure their concerns were addressed. The Board concluded that the existing charge questions had a wide enough scope to encompass the concerns raised by the public speakers. The public SAB/CAAC meeting on ETO is scheduled for November 18-20 at the Hyatt Regency in Crystal City. (Ray Kent, 305-7379)

Webinar on Spray Drift and Volatilization Issues: A webinar, sponsored by the law firm Bergeson and Campbell, was held on October 1 on issues related to spray drift and volatilization. The draft OPP policies, including results of the volatilization screening analysis, were presented followed by an industry perspective on the technical issues on each. Finally, previous Assistant Administrator Jim Aidala presented a commentary on the policy considerations which could occur associated with the implementation of these policies. There was a question and answer period and many of the questions, which were received were similar to the public comments. A list of participants was also provided and most

participants were affiliated with Crop Life America or a registrant organization. (Jeff Dawson 305-7329)

HED Meets with Syngenta to Discuss Inhalation and Field Volatility DCI Requirements for Chlorothalonil: Members of HED (Monique Perron, Kelly Lowe, Billy Smith, and Anna Lowit) and PRD met with representatives from Syngenta to discuss the DCI requirement of a subchronic inhalation study for chlorothalonil. Chlorothalonil is classified as highly toxic via the inhalation route (Category I). Recently, four inhalation studies were reviewed by HED/RAB1, including a 2-week repeat dose inhalation toxicity study. Syngenta provided their perspective of the study results, discussed potential alternatives to conducting a subchronic inhalation study given the highly irritant characteristics of the chemical, and proposed the use of a multiple-path particle dosimetry model to estimate internal dosimetry of chlorothalonil. They presented data regarding particle sizes measured in Respicon samplers as compared to OVS tubes, and droplet size distributions measured using different spray nozzles. Syngenta also provided an overview of their proposed field volatility study to satisfy the Registration Review DCI. (Monique Perron, 347-0395)

Conference call on Convergence of OECD Acute Tox Test Guideline Projects:
Christine Olinger, US National Coordinator for the OECD Test Guideline Program, had a conference call with representatives of AD (Jennifer McLain, Karen Hicks), RD (PV Shah, Bonaventure Akinlosotu, John Redden), OECD, PMRA, and Dow Agrosciences UK, to discuss formation of a single expert group to review two new projects approved at the 2014 meeting of National Coordinators. The UK project is based on an analysis of the dermal tox studies conducted by Dow and the potential for reducing the number of animals used in the study. The US/Canada projects is based on the guidance jointly developed on criteria for waiving acute toxicity studies. The participants agreed that a single expert group could address the both projects and a rough timeline was developed. (Chris Olinger 305-5406)

Conference Call on OECD Cell Transformation Assay Projects: Christine Olinger had a conference call with Jay West of the American Chemistry Council, who has the lead on test guidelines for the OECD Business and Industry Advisory Council (BIAC). There is an item on the agenda of the OECD Joint Meeting next month on the challenges with finishing the ongoing cell transformation assay projects. The OECD has asked for further guidance from the Joint Meeting on the need for these assays and a path forward. BIAC is developing their position and asked for some additional background. (Chris Olinger 305-5406)

<u>Pesticide Use Site Index Web Update:</u> The Pesticide Use Site Index has been updated as of September 2014 and is now available to the public. The Pesticide Use Site Index (<a href="http://www2.epa.gov/pesticide-registration/pesticide-use-site-index">http://www2.epa.gov/pesticide-registration/pesticide-use-site-index</a>) provides information on all agricultural and non-agricultural pesticide use

sites and use patterns. These use patterns help identify which data requirements (40 CFR Part 158) are needed for pesticide registration. There are 14 major pesticide use patterns and indices can be searched by commodity, use pattern such as terrestrial food crop or by Crop group. This is the first update since 2007, when the data requirement rule for conventional pesticides was finalized. With this recent update, new use sites have been added and the tables reformatted for easier viewing. (Bernard Schneider, 305-5555; Yuen-Shaung Ng, 308-8120; Vera Au, 308-9069)

**EPA Updates Dietary Exposure Analysis Model, DEEM/Calendex:** EPA has updated the Dietary Exposure Evaluation Model-Food Commodity Intake Database (DEEM-FCID)/Calendex to include more recent food consumption data and made this available to the public. This version contains more recent food commodity consumption data derived from the National Health and Nutrition Examination Survey/"What We Eat in America" (NHANES/WWEIA) for 2005-2010 (http://www.cdc.gov/nchs/nhanes.htm). It replaces the 2003-2008 NHANES/WWEIA data used in the prior version (DEEM-FCID/Calendex v. 3.18/9.14) of the software. Those wishing to access the consumption, recipe and associated demographic data files used as the basis of FCID can do so on the University of Maryland's Joint Institute for Food Safety and Nutrition (JIFSAN) website (http://fcid.foodrisk.org/). JIFSAN has updated the database to include the 2005-2010 raw data provided to them by HED, and has several online applications that make it easier for the public to access and interpret the data, including a consumption calculator that simplifies routine food and food commodity consumption queries. To accommodate additional internal and external testing as well as transition within EPA's regulatory process, both this version (DEEM-FCID/Calendex v. 4.02/10.00) and the previous version (DEEM-FCID/Calendex v. 3.18/9.14) will be operable until March 31, 2015. The DEEM-FCID/Calendex software can be found and downloaded at http://www.epa.gov/pesticides/science/deem/. (David Hrdy, 305-6990; Matthew Crowley, 305-7606)

Overview of the 2014 Joint Meeting on Pesticide Residues: The 2014 Joint Meeting on Pesticide Residues (JMPR) evaluated over 30 pesticides for toxicology and/or residue chemistry, making numerous recommendations to CCPR for Codex MRLs. In some cases, the Meeting struggled with a lack of toxicology data for pesticide metabolites deemed to be important from an exposure standpoint; in one case this led to no recommendations for a particular active ingredient. Given the increasing demand for JMPR recommendations and the relative underrepresentation from North America, the Agency may benefit from sending more experts to the Meeting. (Michael Doherty, 305-1031)

# **REGISTRATION DIVISION**

Chemical	Company	Registration	Action	Due Date	Response				
TI E	<u> </u>	Number	Code*		Date				
The Fungicide Branch granted:									
Pyraclostrobin	BASF Company	7969-368	R300	12/29/2014	10/1/2014				
Maryam Muhammad, 703/347-0301									
The Herbicide Branch	granted:								
Dichlobenil	RCS II Inc.	90745-1	R300	9/23/2014	9/23/2014				
Maggie Rudick, 703/347-02									
Chlorimuron	Sharda USA LLC	83529-40	R300	10/27/2014	10/2/2014				
Sarah Meadows, 703/347-0505									
Penoxsulam	Howard Johnson's Enterprises, Inc.	32802-81	R301	10/3/2014	10/1/2014				
	Shanta Adeeb, 703/347-0502								
Glufosinate	United Phosphorus, Inc.	70506-310	R310	10/14/2014	9/30/2014				
	•	Betha	ny Benbov	v, 703/347-8072					
Flumioxazin	E. I. DuPont de Nemours and Company	352-757	R340	11/18/2014	9/30/2014				
Mindy Ondish, 703/60				703/605-0723					
The Insecticide Branc	h granted:R340								
Piperonyl butoxide	Wechem Inc.	34370-1	R300	9/29/2014	9/26/2014				
Carlyn Petrella, 703/347-0439									
Zeta-Cypermethrin	FMC Corporation Agricultural Products Group	279-3289	R340	10/11/2014	9/26/2014				
		BeWanda	Alexande	r, 703/305-7460					
Flubendiamide	Nichino America, Inc.	71711-26	R351	11/12/2014	9/30/2014				
		Carn	nen Rodia.	703/306-0327					

The Insecticide-Rodenticide Branch granted:								
Novaluron	Control Solutions, Inc.	53883-350	R310	9/30/2014	9/29/2014			
Jennifer Gaines, 703/305-5967								
Spirotetramat	Bayer CropSceince LP	264-1170	R314	10/6/2014	9/29/2014			
Jennifer Urbanski, 703/347-0156								
		12455-69	R340	10/10/2014	9/26/2014			
		12455-76						
Bromadiolone	Bell Laboratories, Inc.	12455-86						
		12455-96	R340	12/1/2014	9/30/2014			
		12455-143						
Jacquelyn Marchese, 703/347-0235								

## **PRIA Categories**

R300 – New product; identical or substantially similar in composition and use to a registered product; no data review or only product chemistry data; cite-all data citation or selective data citation where applicant owns all required data or submits specific authorization letter from data owner; category also includes 100% repackage of registered end-use or manufacturing-use product that requires no data submission or data matrix (3) (4); R301 – New product; or similar combination product (already registered) to an identical or substantially similar in composition and use to a registered product; registered source of active ingredient; selective data citation only for data on product chemistry and/or acute toxicity and/or public health pest efficacy, where applicant does not own all required data and does not have a specific authorization letter from data owner(2) (3); R310 – New end-use or manufacturing-use product with registered source(s) of active ingredient(s); includes products containing two or more registered active ingredients previously combined in other registered products; requires review of data package within RD only; includes data and/or waivers of data for only: product chemistry and/or acute toxicity and/or public health pest efficacy and/or child resistant packaging(2) (3);

R314 – New end use product containing two or more registered active ingredients never before registered as this combination in a formulated product; new product label is identical or substantially similar to the labels of currently registered products which separately contain the respective component active ingredients; requires review of data package within RD only; includes data and/or waivers of data for only: product chemistry and/or; acute toxicity and/or; public health pest efficacy and/or; child resistant packaging. (2) (3); and R340 – Amendment requiring data review within RD (e.g., changes to precautionary label statements)(2) (3)